## Unmasking Masks in Makkah: Preventing Influenza at Hajj

Each year more than 2 million people from all over the world attend the Hajj pilgrimage to Saudi Arabia. At least 60% of them develop respiratory symptoms there or during outward or homebound transit [1, 2]. During recent interpandemic years, approximately 1 in 10 pilgrims with respiratory symptoms in Makkah have had influenza detected by polymerase chain reaction tests of respiratory samples [3, 4]. Pneumonia is the leading cause of hospitalization at Hajj, accounting for approximately 20% of diagnoses on admission [5]. Hajj 2009 took place in November in the middle of the influenza A H1N1 pandemic (pH1N1). However, a recent report suggests that the prevalence of pH1N1 was 0.2% (n = 1) among 519 arriving pilgrims and 0.1% (n = 2) among 2699 departing pilgrims [6], probably because of heightened infection control and preexisting cross-immunity among pilgrims, most of whom would have been exposed to H1N1 before 1957 [7].

Experience from an ear, nose, and throat (ENT) clinic in Makkah suggested that only 77 of 3087 patients (2.5%) who attended with ENT symptoms had suspected pH1N1 based on history of contact with a patient with pH1N1 and clinical symptoms of influenza-like illness (ILI); however, laboratory testing for influenza virus was not undertaken [8]. The efficacy of influenza vaccine is dependent on matching the vaccine and circulating influenza strains. Because the pH1N1 vaccine was not largely available in time for Hajj 2009, protection was dependent on previous exposure to H1N1 influenza A virus and nonpharmaceutical interventions such as face masks [2].

Historically, face masks have been used to prevent or reduce nosocomial transmission of pandemic influenza since, at least, the time of Spanish influenza in 1918. Nurses who wore specially designed face masks and changed them every 2 hours experienced lower infection rates than those who did not [9]. Recent experiments confirm that surgical masks and respirators can filter influenza virus, although observational studies or clinical trials have not yet clearly demonstrated the effectiveness of plain surgical masks in household or healthcare settings [10–16].

The role of surgical masks, respirators, and/or hand hygiene in preventing ILI has been examined in at least 15 studies including 5 randomized controlled trials (RCTs). These compared "plain surgical mask" with "no intervention" against ILI [10–14]. In 4 of these RCTs influenza was laboratory confirmed [10–13]. Metadata from these studies indicated that wearing surgical masks did not change the frequency of laboratory-confirmed influenza (Figure 1). The findings may have been due to limitations and biases in study design [10–14]. A common limitation of all studies was small sample size. Despite similar study design, the sample-size calculations were based on different assumptions, and the studies lacked the power to detect a difference in incidence of laboratory-confirmed influenza.

At least 2 observational studies at the Hajj have examined the role of masks in preventing acute respiratory infection. One of these studies evaluated the role of face masks among pilgrims at the 2002 Hajj [15], when a protective effect was shown in men but not in women. The other study evaluated the use of face masks worn by healthcare workers at the 2005 Hajj in preventing acquisition of acute respiratory infection when protective effectiveness was nonsignificant [16].

The Hajj congregation of more than 2 million people who stay for 5 days in 25 000 tents in Mina, a valley within Makkah city, provides a unique opportunity to conduct RCTs of mask effectiveness to avoid sample size and design limitations.

During Hajj 2011 the 5-day stay in Mina is from 4 to 8 November. We are undertaking a pilot study to examine the feasibility of a cluster RCT of mask use among Australian pilgrims. Assuming success of this pilot trial, we plan to set up large RCT involving pilgrims from several countries in subsequent years. We are seeking expressions of interest for a multinational collaboration and would be pleased to hear from possible collaborators.

## Note

***Potential conflicts of interest.*** R. B. has received financial support from the pharmaceutical companies CSL, Sanofi, GlaxoSmithKline, Novartis, Roche, and Wyeth to conduct research and attend and present at scientific meetings. Any funding received is directed to a National Centre for Immunisation Research

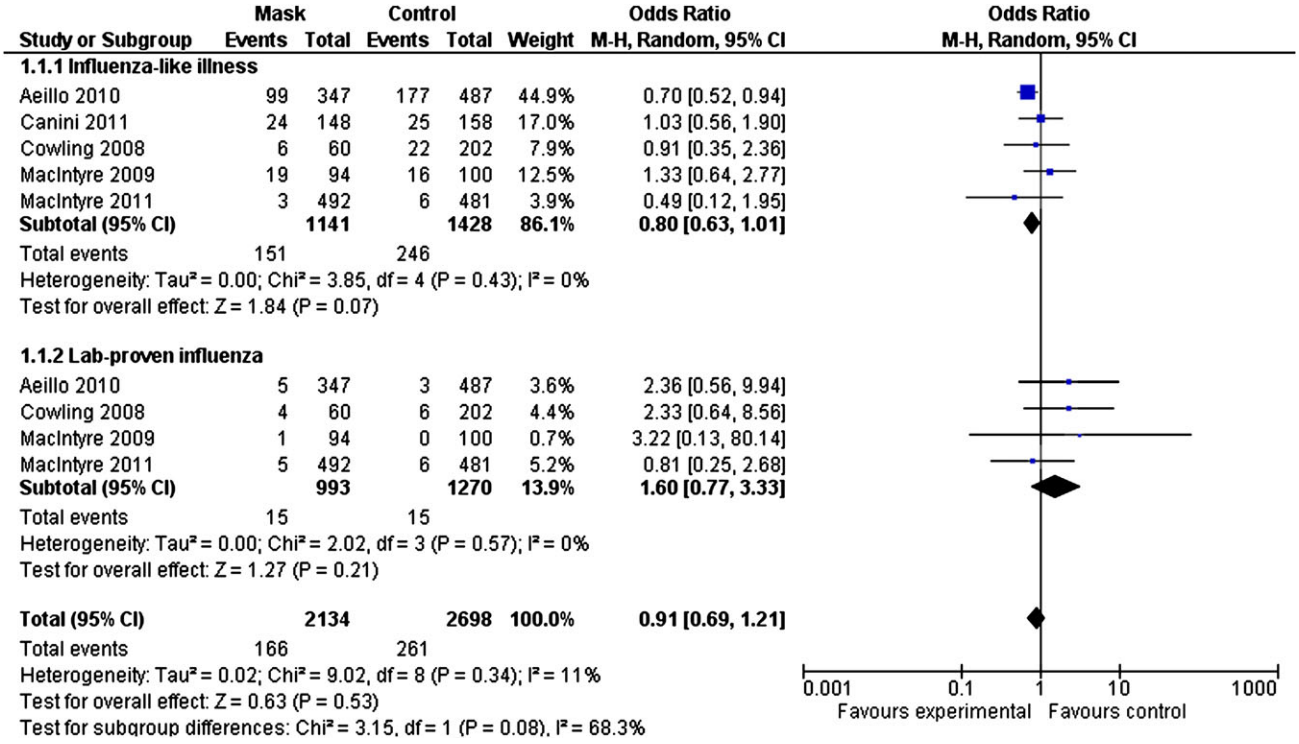


**Figure 1.** Comparison between mask and control groups in randomized controlled trials. Abbreviations: CI, confidence interval; df, degrees of freedom; M-H, Mantel–Haenszel.

and Surveillance research account at The Children's Hospital at Westmead and is not personally accepted by R. B. L. H. conducts sponsored research for several vaccine manufacturers; has received support to attend conferences from GlaxoSmithKline and Sanofi Pasteur; and has been a member of a vaccine advisory board for Novartis. All funds received are directed to the National Centre for Immunisation Research and Surveillance of Vaccine Preventable Diseases, The Children's Hospital at Westmead. J. N.-V.-T. has received funding to attend influenza-related meetings, lecture and consultancy fees, and research funding from several influenza antiviral drug and vaccine manufacturers. All forms of personal remuneration ceased in September 2010, but influenza-related research funding from GlaxoSmithKline, F. Hoffmann-La Roche, and AstraZeneca remains current. He is a former employee of SmithKline Beecham plc (now GlaxoSmithKline), Roche Products Ltd, and Aventis-Pasteur MSD (now Sanofi-Pasteur MSD), all prior to 2005, with no outstanding pecuniary interests by way of shareholdings, share options, or accrued pension rights. All other authors report no potential conflicts.

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